UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF TEXAS
HOUSTON DIVISION

UNITED STATES OF AMERICA	§	
ex rel. JOHN KING and	§	
TAMMY DRUMMOND, *et al.*,	§	
Plaintiffs,	§	
	§	
v.	§	CIVIL ACTION H-06-2662
	§	
SOLVAY S.A., *et al.*,	§	
Defendants.	§	

ORDER

Pending before the court is a supplemental motion for partial summary judgment filed by defendant Solvay Pharmaceuticals, Inc. ("SPI") seeking summary judgment on relators John King and Tammy Drummond's (collectively, "Relators") Pharmacy and Therapeutics Committee ("P&T Committee") influence theory.[1] Dkt. 395. Relators filed a response, SPI filed a reply, the State of California filed a statement of interest, and SPI filed a response to California's statement of interest. Dkt. 420 (sealed response); Dkt. 438 (redacted response); Dkt. 456 (sealed reply); Dkt. 457 (redacted reply); Dkt. 463-1 (statement of interest); Dkt. 468 (response to statement of interest). After considering these filings and the applicable law, the court is of the opinion that the supplemental motion should be GRANTED.

I. BACKGROUND

This is a False Claims Act case relating to SPI's promotion of three drugs that it manufactures—Aceon, AndroGel, and Luvox (the "Drugs at Issue"). Relators contend, among other things, that SPI "actively targeted members of states' pharmaceutical and therapeutic ("P&T")

[1] SPI is now known at AbbVie Products, LLC. Dkt. 394 at 1 n.1.

committees and pushed its off-label messages for its drugs in an effort to obtain placement of its drugs on state Medicaid formularies" or Preferred Drug Lists ("PDLs"). Dkt. 154 ¶ 287. Theoretically, if a drug is on the PDL, it can be prescribed without restrictions such as having to obtain prior authorization from the state Medicaid program, thus increasing the amount of prescriptions physicians write for the drugs. Relators assert that SPI's sales force "showered the [P&T committee] member with offers of gifts, dinners, and every kind of bribe in exchange for hearing [SPI's] off-label details." *Id.* Relators contend that "[w]ooing P&T committee members was discussed openly and earnestly on periodic conference calls with upper management," and that sales representatives were encouraged to "wine and dine" these physicians. *Id.* ¶ 289.

On October 7, 2014, SPI filed it's a motion for partial summary judgment seeking summary judgment in its favor on Relators' claims that SPI unlawfully influenced state P&T Committees to place the Drugs at Issue on state PDLs or formularies (the "P&T Committee Influence Theory"). Dkt. 303. On January 23, 2015, the court issued an order granting in part and denying in part SPI's motion for partial summary judgment. Dkt. 378. The court granted summary judgment as to the P&T Committee Influence Theory for various states as outlined in the order. Dkt. 378 at 5. It denied the motion, without prejudice, as to SPI's claims that certain states did not have PDLs, that the Drugs at Issue were not on the PDLs, or that the PDLs were unavailable. *Id.* at 12. The court noted that it was unclear from the briefing and evidence submitted whether any of the states that had P&T committees had any type of formulary managed by a P&T committee other than a PDL.[2] *Id.* at 10. SPI has now filed a supplemental motion seeking summary judgment on the Relators' claims that

[2] A "formulary," as used by the parties in this case, is a generic term for a PDL or document that is similar to a PDL.

SPI improperly influenced P&T committees in the remaining states. Dkt. 397. First, SPI asserts that the only available evidence shows that, during the relevant time period, Aceon was listed on a PDL or formulary in only 11 states, AndroGel was listed in only nine states, and no state listed Luvox. Dkt. 397. Thus, SPI argues that any claims under the P&T Committee Influence Theory as to any other states must be dismissed. *Id.* Second, SPI asserts that Relators concede, through their damages expert, that there are only four states still at issue for the P&T Committee Influence Theory for Aceon, one state for AndroGel, and one state for Luvox. Third, SPI argues that there are no genuine issues of material fact as to whether fraud or improper influence led the P&T committees in the remaining states to include any of the Drugs at Issue on their state PDLs or formularies. *Id.*

Relators argue that they have evidence that SPI wined and dined individuals on state P&T committees and supplied them with various off-label falsehoods about the Drugs at Issue. Dkt. 420. Relators concede that, in light of the court's previous ruling on the P&T Committee Influence Theory (Dkt. 373), that they are currently only asserting claims under the P&T Committee Influence Theory for the following drugs and states:

> Luvox: California and Kentucky
> Aceon: Alabama, Florida, Illinois, Iowa, Louisiana, South Carolina, and West Virginia
> AndroGel: Florida, Louisiana, Maryland, Ohio, Tennessee, Texas, West Virginia, and Wisconsin.

Id. They then provide evidence that they contend creates issues of material fact that each of these states had a formulary or PDL during the relevant timeframe, that SPI potentially influenced P&T committee members in those states, and that the Drugs at Issue were at some point given preferred status in those states. *Id.* Relators argue that SPI is asking the court to make a credibility finding and weigh evidence in SPI's favor, but that if the court construes Relators' evidence in the light most

favorable to Relators, as it must, then the court should deny SPI's motion for partial summary judgment. *Id.*

SPI responds first that summary judgment should be granted as to all but the fourteen states Relators assert are still at issue. Dkt. 456. Second, SPI argues that Relators did not respond to its argument that Relators' expert only provides evidence of an impact on state Medicaid programs for four states for Aceon, one state for AndroGel, and one state for Luvox, so the claims as to all other states should be dismissed. *Id.* Third, SPI points out that Relators have come forward with only a few documents that show the three drugs were on state PDLs or formularies during the relevant timeframe and that SPI is entitled to summary judgment as to any state and time period where the Drugs at Issue were not listed as preferred. *Id.* Finally, SPI argues that it is entitled to summary judgment on the P&T Committee Influence Theory for the remaining states because Relators' evidence does not support a causal connection between any alleged "wooing" of P&T Committee members and the placement of the Drugs at Issue on a PDL or formulary. *Id.*

The State of California does not have a P&T Committee, but it has filed a statement of interest seeking a ruling that its Contract Drug Advisory Committee serves the same purpose as a P&T Committee. Dkt. 463-1. SPI responds that, regardless, California's committee is not called a P&T Committee, and the court's prior order makes clear that the complaint refers only to groups called "P&T Committees." Dkt. 468. Thus, SPI urges the court to grant summary judgment as to any claim that Relators unlawfully influenced the California P&T Committee to place Aceon, Luvox, or AndroGel on its formulary. *Id.*

The court will first set forth the legal standard. It will then address California's statement of interest. Next, it will discuss the states not addressed in Relators' opposition. Finally, it will

determine whether Relators have demonstrated that there is an issue of material fact on their claims that SPI unlawfully influenced P&T Committee members in the remaining states.[3]

II. LEGAL STANDARD

A court shall grant summary judgment when a "movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(c). "[A] fact is genuinely in dispute only if a reasonable jury could return a verdict for the non-moving party." *Fordoche, Inc. v. Texaco, Inc.*, 463 F.3d 388, 392 (5th Cir. 2006). The moving party bears the initial burden of demonstrating the absence of a genuine issue of material fact. *Celotex Corp. v. Catrett*, 477 U.S. 317, 323, 106 S. Ct. 2548 (1986). If the party meets its burden, the burden shifts to the non-moving party to set forth specific facts showing a genuine issue for trial. Fed. R. Civ. P. 56(e). The court must view the evidence in the light most favorable to the non-movant and draw all justifiable inferences in favor of the non-movant. *Envtl. Conservation Org. v. City of Dall., Tex.*, 529 F.3d 519, 524 (5th Cir. 2008).

III. CALIFORNIA'S STATEMENT OF INTEREST

The State of California filed a statement of interest to clarify how California's Medicaid plan works. Dkt. 463-1. Specifically, California's Medicaid system ("Medi-Cal") has a "Contract Drug List" rather than a PDL. *Id.* Drugs on the Contract Drug List do not require prior authorization. *Id.* A Contract Drug Advisory Committee makes recommendations regarding which drugs should be on the Contract Drug List. *Id.* The State of California requests that this court find that the Medi-Cal

[3] The court has already granted summary judgment as to all claims relating to AndroGel under another theory. Dkts. 386, 585. However, the court addresses AndroGel in this order in an abundance of caution.

Contract Drug List is a formulary for Medi-Cal and that the Medi-Cal Contract Drug Advisory Committee serves as a "P&T Committee." *Id.*

SPI argues that the court has already ruled that Relators' claims are only viable to the extent they can show that SPI improperly influenced groups specifically called "P&T Committees," not groups that serve the same purpose as a P&T Committees but have a different name. Dkt. 468 (citing Dkt. 378 at 6–7).

The court agrees with SPI. While certainly the California Drug Advisory Committee, like the state Drug Utilization Review boards the court mentioned in its previous order on the P&T Committee Influence Theory, may serve the exact same purpose as a P&T Committee, Relators were required to state their fraud claims with particularity under Federal Rule of Civil Procedure 9(b), and they have had many years to do so. The live complaint specifically refers to state "P&T Committees," and, as the court has already ruled, Relators' P&T Committee influence claims extend only to states that had a group known as a "P&T Committee." Relators did not extend the theory to P&T Committees *or similar groups* in any iteration of their complaint, and the court will not read it into the complaint at this late date. Accordingly, SPI's motion for summary judgment as to Relators' P&T Committee influence theory as it pertains to California—for all three Drugs at Issue—is GRANTED.

IV. STATES NOT LISTED IN THE OPPOSITION

Relators contend in their opposition that, during the relevant time period, Luvox was listed on PDLs or formularies in two states, that Aceon was listed on PDLs or formularies in seven states, and AndroGel was listed on PDLs or formularies in eight states. Dkt. 420. To the extent Relators' complaint asserts claims under its P&T Committee Influence Theory for other states and drugs, and for the District of Columbia, those claims are DISMISSED WITH PREJUDICE, as Relators have not

come forward with an issue of material fact that P&T committees in those states were influenced to place one of the three Drugs at Issue on a PDL or formulary.

V. THE REMAINING STATES

The states that remain for each drug at issue are:

> Luvox: Kentucky
> Aceon: Alabama, Florida, Illinois, Iowa, Louisiana, South Carolina, and West Virginia
> AndroGel: Florida, Louisiana, Maryland, Ohio, Tennessee, Texas, West Virginia, and Wisconsin

SPI contends that summary judgment should be granted for all of these drugs and states, too, because (1) Relators' expert only demonstrated impact on four state Medicaid programs for Aceon, one for Luvox, and one for AndroGel; (2) even for these states, summary judgment should be granted as to time periods that the drugs were not on the PDLs or formularies; and (3) Relators' evidence of "wooing" of the P&T Committee members in each of the remaining states is insufficient to support causation. The court will address these arguments as they relate to Luvox, Aceon, and AndroGel, *in seriatim*.

A. Luvox

The only states Relators contend are still at issue for this theory with regard to Luvox are California and Kentucky. The court has already determined that Relators' claim under this theory relating to California must be dismissed. With regard to Kentucky, Relators contend that SPI used a physician with company ties to influence Kentucky's Drug Formulary Advisory Board to add Luvox to Kentucky's Medicaid formulary without prior authorization effective May 1996. Dkt. 420. Relators provide evidence that they assert demonstrates that the addition of Luvox to the formulary caused Luvox sales in Kentucky to increase dramatically. *Id.* The problem is, like with California,

Kentucky did not have a "P&T Committee." While its Drug Formulary Advisory Board may have served the same function as a P&T Committee, Relators did not plead that Kentucky's P&T Committee *or a similar group* was influenced. SPI's motion for summary judgment on Relators' claim that SPI improperly influenced members of Kentucky's P&T Committee to add Luvox to Kentucky's formulary is GRANTED.

B. Aceon

The Food and Drug Administration ("FDA") approved Aceon, the brand name for perindopril, for "essential hypertension," or high blood pressure, in 1993. Dkt. 154 at 53 (citing the Aceon label). Aceon is in a drug class known as "ACE inhibitors," which Relators contend are drugs that "lower blood pressure by inhibiting the activity of angiotensin converting enzyme ("ACE"), which converts angiotensin I to angiotensin II," and that by "inhibiting ACE and thereby decreasing the production of angiotensin, the blood vessels dilate and blood pressure is lowered." *Id.* at 53 n.16. In 2005, the FDA additionally approved Aceon for use "in patients with stable coronary artery disease to reduce the risk of cardiovascular mortality or non-fatal myocardial infarction." *Id.* at 53; *see* http://www.accessdata.fda.gov/drugsatfda_docs/label/2005/020184s011lbl.pdf (Aceon prescription insert, revised May 2005). Relators contend that any Aceon advertising relating arterial wall compliance ("AWC"),[4] diabetic kidney,[5] or the PROGRESS study for prevention of secondary

[4] The AWC claims were allegedly claims that "Aceon delivered a structural change in all arteries by remodeling them," which was based on animal research and not a claim approved by the FDA. Dkt. 154 at 53.

[5] Relators contend that SPI advertised Aceon's "complete 24-hour protection of blood pressure" to show that it offered "complete protection of a patient's kidneys," as when blood pressure medications wear off, the elevated blood pressure is allegedly problematic for the patient's kidneys. Dkt. 154 at 56. Relators contend that SPI had no data supporting its diabetic kidney claims and studies about whether Aceon provides 24-hour protection have had mixed results. *Id.*

stroke,[6] is illegal off-label marketing. Dkt. 154 at 53.

1. Nationwide Marketing

Relators assert that SPI distributed the AWC and PROGRESS messages to P&T committees methodically. Dkt. 420 at 11. First, they discuss formulary kits or dossiers that SPI provided to P&T committees. These formulary kits or dossiers contained off-label information about the Drugs at Issue, including, with regard to Aceon, the AWC message and, likely, PROGRESS. Dkt. 420 at 11 & Ex. 155 at 48–49. Relators argue that these messages were part of a nationwide effort to get Aceon on as many plans as possible. Dkt. 420 at 12.

Relators next assert that SPI promulgated the AWC message in an October 4, 1999 supplement to the *American Journal of Managed Care*. *Id.* & Ex. 31. According to an SPI interoffice memorandum, the supplement was distributed, along with the journal, to approximately 28,400 P&T committee members.[7] Dkt. 20, Ex. 31 at 158488. The supplement reported the proceedings at a symposium that, according to Relators, was chaired by a physician who was an SPI consultant; Relators contend that the other participants were either official or unofficial SPI-paid consultants. Dkt. 420 at 12–13. Relators note that the AWC representations in the supplement were off-label and argue that they were also misleading, pointing out that the FDA had specifically advised SPI three

[6] *See infra* Note 14 for more information on the PROGRESS trials.

[7] The memorandum specifically warns the SPI employees who received it not to use the supplement in a promotional manner. *Id.*

months earlier that certain claims relating to AWC were misleading.[8] *Id.* at 13 (citing Dkt. 111-4 (Ex. 19)).

Relators additionally contend that SPI's 2002 Aceon Business Plan reflects SPI's nationwide plan to spread these off-label messages. Dkt. 420 at 13–14. One of the objectives in the plan is to "[i]ncrease unrestricted reimbursement status for ACEON by targeted managed care plans." Dkt. 111-16, Ex. 119 at 49410. The strategies include leveraging "the PROGRESS clinical data with managed care organizations to improve formulary status." *Id.*

SPI argues that none of this evidence creates genuine issues of material facts as to whether SPI unlawfully wooed P&T committee members and the wooing influenced the committees' decisions. Dkt. 457. As to the dossiers, SPI contends that there is no evidence that its provision of dossiers to P&T committees ran afoul of FDA requirements or that the dossier impacted any committee's decision to include Aceon on a formulary. Dkt. 457. SPI's corporate representative testified that the dossiers were sent at the request of the P&T committees when the committees "asked for all available clinical data" for the drug. Dkt. 420, Ex. 155 at 28. An SPI executive who worked in the Medical Information department testified that a "dossier did not require staying on label" because they are "not promotional" and that the information was compiled by doing literature

[8] In a July 29, 1999 letter, the FDA discussed SPI's request for comments on its proposed launch promotional materials for Aceon. Dkt. 111-4 (Ex. 19). The letter states that the FDA's Division of Drug Marketing, Advertising, and Communications "would consider [SPI's] presentation of claims and representations related to arterial compliance to be misleading" because the effect "has not been conclusively demonstrated in clinical trials" and "the clinical significance of an effect on arterial compliance has not been established." Additionally, the FDA noted that "the effect of Aceon on arterial wall compliance, demonstrated in animal models, may not be applicable to humans." *Id.* Interestingly, the FDA did not recommend that SPI avoid discussing AWC altogether. Instead, it recommended revising the discussion to "be consistent with approved product labeling," which discusses the animal models. *Id.*

searches and providing references. *See* Dkt. 457 at 11 n.9 (referring the court to Dkt. 411); Dkt. 412-1 at 292–93. With regard to the supplement, SPI points out that there is no evidence that the supplement was distributed to state P&T committees (as opposed to other managed care P&T committees), that SPI was the distributor (as opposed to the journal's publisher), or that any state Medicaid P&T committee member who voted to include Aceon on a formulary received the supplement. Dkt. 457 at 10. Additionally, SPI asserts that there is no evidence that the supplement has a temporal connection to any P&T committee's decision to include Aceon on a formulary. *Id.* at 11. As far at the business plan, SPI contends that business planning discussions are not evidence of causation. Dkt. 457 at 12.

A reasonable jury could infer from this evidence that SPI had a business goal to obtain formulary or PDL placement of Aceon on state and managed care formularies or PDLs. However, while Relators have shown that SPI's dossiers likely contained off-label information, they have not provided any evidence showing that such information in a document requested by the P&T committees was prohibited or that sending the dossiers constituted unlawful promotion. The evidence that SPI violated some sort of promotional regulation with regard to the supplement is also lacking. Here, the evidence shows that the supplement was sent out, by some entity, along with the journal. SPI sales representatives, however, were warned that the supplement could not be used to promote Aceon.

Relators point to some of this evidence in relation to their discussions of SPI's alleged unlawful influence of the P&T committee members of specific states. The court will consider, when discussing the claims as to each state, whether any of this evidence is sufficient, when considered together with the evidence Relators provide for each state, for a reasonable jury to conclude that SPI's

activities improperly influenced P&T committees to add Aceon to that state's formulary or PDL. First, however, the court turns to SPI's argument relating to whether the Aceon claims for some states should be dismissed because Relators' expert did not calculate damages for those states.

2. Expert Evidence

Relators state in their response that they are only asserting claims as to Alabama, Florida, Illinois, Iowa, Louisiana, South Carolina, and West Virginia for Aceon. Dkt. 420. SPI contends that Relators' claim that SPI unlawfully influenced P&T Committee members in Alabama, Iowa, and South Carolina must be dismissed because Relators conceded through their expert that they were not pursuing these claims with regard to these states. Dkts. 397, 456. SPI points out that Relators' damages expert stated, in her amended report, that Relators' counsel advised her to "keep" eleven of the states for which she had calculated damages related to Aceon being placed on a PDL or formulary, and that she could not calculate actual drug sales trends for all eleven states due to the timing of the prior authorization requirements.[9] Dkt. 397 & Ex. 2. She calculated damages using actual sales data for Florida, Illinois, Louisiana, and West Virginia, and she used an average of the data from those four states to estimate prior authorization damages for the remaining states, including Alabama, Iowa, and South Carolina.[10] Dkt. 397, Ex. 2.

SPI specifically requested information as to which states Relators contended were still viable after the court's previous order on this theory, and Relators provided the expert report in response.

---

[9] Relators have since abandoned their claims as to four of the eleven states they told their expert to "keep," as they concede in their opposition that only seven states remain at issue for Aceon for this theory.

[10] The other states that she estimated damages using an average from other states are Connecticut, Delaware, Idaho, and Maryland. Dkt. 420, Ex. 2 ¶ 4. Relators do not discuss these states in their opposition. *See* Dkt. 420.

See Dkt. 397 at 17. SPI asserts that Relators' provision of this report along with the expert's indication that Relators' counsel instructed her to only "keep" eleven states is a concession by Relators that they lack evidence as to all states except the four states for which their expert calculated actual damages. *Id.* Relators did not address this assertion in their response (*see* Dkt. 420), and SPI argues in its reply that Relators have thus conceded the point. Dkt. 456 at 4. However, the argument in SPI's motion that only the four states for which actual damages are calculated are still viable is flawed, as the expert clearly stated in her report that she estimated damages as to the other states. *See* Dkt. 397, Ex. 2. SPI has cited no authority indicating that summary judgment is required on a claim simply because an expert estimated damages. The court will thus consider Relators' other evidence with regard to all of the states Relators contend in their opposition remain viable states for this theory, as the expert either estimated damages or calculated actual damages for each of these states.

3. Alabama

Relators contend that SPI exerted undue influence on Alabama Medicaid's P&T Committee members and won unmerited favorable placement on Alabama's PDL. Dkt. 420 at 14. They provide a call note indicating that an SPI sales representative attended a "Dine & Dash" on June 7, 2001, with a physician who would later become the chairperson of Alabama's P&T Committee.[11] Dkt. 420, Ex. 33 (call notes); Dkt. 420, Ex. 32 (list of Alabama P&T Committee members). The notes indicate that the sales representative "detailed Aceon, AndroGel, and [another drug]." *Id.* Relators also provide a note indicating that a different SPI sales representative had various discussions about Aceon

[11] Relators do not provide more information about what a Dine & Dash is in their response. However, in their Fifth Amended Complaint, Relators describe a "Dine 'N Dash" as SPI inviting physicians to a popular restaurant to pick up dinner for their families. As the physicians waited for their take-out meals, SPI allegedly gave a sales pitch about SPI drugs. Dkt. 154 at 143–44.

with the same physician on November 29, 2001, February 26, 2002, May 5, 2003, and October 23, 2003. Dkt. 420, Ex. 33.

Relators produce call notes relating to a different P&T Committee member that was registered for the Aceon Community Trial ("ACT") on April 17, 2000.[12] Dkt. 420, Ex. 34. Sales representatives discussed ACT with the physician on July 20, 2000, January 21, 2003, February 20, 2003, April 17, 2003, and September 3, 2003. *Id.* The physician also attended "Lunch and Learns," and one sales representative scheduled a dinner with the physician in August 2003.[13] *Id.* Two other Alabama P&T Committee members heard about AWC from an SPI sales representative on February 17, 2000, and a different member of the P&T Committee discussed ACT with an SPI sales representative on April 24, 2003. Dkt. 420, Exs. 35, 37.

Additionally, Relators provide a copy of a February 2002 business plan for the Birmingham District in which the district manager states that he was "[w]orking with State P&T chairman to have Aceon included on [the] preferred Ace Inhibitor list." Dkt. 420, Ex. 38 at D02784. The same

---

[12] The Aceon Community Trial ("ACT") was an "open-label, community-based investigation of how well [Aceon] controls blood pressure in various groups." Dkt. 111, Ex. 123. According to a March 20, 2000, draft of an SPI memorandum, SPI was going to send study information to 9,000 community-based physicians to determine their interest in being an investigator for the study. *Id.* Relators contend in their Fifth Amended Complaint that SPI had orientation sessions for the study at luxury hotels and paid physicians to attend the sessions. Dkt. 154 ¶ 335. Relators additionally contend that SPI "saw ACT . . . as essentially physician-enrollment programs." *Id.* However, Relators do not provide any evidence of these contentions in their opposition.

[13] Relators do not provide any details about what a "Lunch and Learn" is, but the Fifth Amended Complaint indicates that "Lunch-N-Learns" were programs where SPI would bring food from a popular restaurant to physicians and their staffs and, while they were eating, allegedly disseminate off-label information about the Drugs at Issue. Dkt. 154 at 143.

manager met with the P&T committee chairman to discuss Aceon and PROGRESS data in March 2002.[14] *See* Dkt. 111-15, Ex. 101 (email discussing the "very productive meeting").

Relators contend that Aceon was listed on Alabama's PDL in 2002 and remained on the PDL through at least 2008.[15] Dkt. 420 at 16 & n.11. However, the first actual PDLs provided by Relators start in February 2004. *See* Dkt. 111, Ex. 40.

SPI points out first that the list of physicians who were on the Alabama P&T committee does not include dates, so it is unclear whether the physicians to whom Relators' call notes refer were even on the P&T Committee during the relevant time. Dkt. 456 at 13. Additionally, SPI argues that there

---

[14] The PROGRESS trials, which stands for "perindopril protection against recurrent stroke study," were "designed to determine the effects of a blood-pressure-lowering regimen in hypertensive and non-hypertensive patients with a history of stroke or transient ischaemic attack." Dkt. 111, Ex. 32 (Progress Collaborative Group, *Randomised Trial of a Perindopril-Based-Blood-Pressure-Lowering Regimen Among 6105 Individuals with Previous Stroke or Transient Ischaemic Attack*, 358 The Lancet 1033 (Sept. 29, 2001)). Aceon is the brand name for perindopril erbumne. *Id.* The study found that a combination of perindopril and indapamide reduced blood pressure and stroke risk, but "[s]ingle-drug therapy reduced blood pressure by 5/3 mm Hg and produced no discernable reduction in the risk of stroke." *Id.* at 1033. The journal publishing the study results recommended that physicians consider "[t]reatment with these two agents . . . routinely for patients with a history of stroke or transient ischaemic attack, irrespective of their blood pressure." *Id.* Relators contend that these results were a "disappointment," but that SPI decided to give its sales force the message that "PROGRESS was a breakthrough drug and must be rigorously promoted." Dkt. 154 at 61.

[15] Relators rely on an internal email to demonstrate that Aceon was placed on the Alabama PDL in 2002. *See* Dkt. 420 at 16 n.11 (citing Dkt. 111, Ex. 101 for 2002). However, this email contains an account of a sales representative who attended the March 2002 Alabama Medicaid meeting. Dkt. 111, Ex. 101. The sales representative reports on various statements made by the P&T committee chairperson, including that Aceon had been added "to the brand preferred list." *Id.* While this statement may be somewhat probative on Aceon being added to the Alabama PDL at some point in 2002, it is clearly hearsay and cannot serve as adequate summary judgment evidence that Aceon was indeed placed on the 2002 PDL. *See* Dkt. 456 at 8 n.5 (SPI's objection to the hearsay). The evidence cited for 2003 is actually an AndroGel prescription insert and has nothing to do with Aceon being added to the Alabama PDL. *See* Dkt. 420 at 16 n.11 (citing Dkt. 111, Ex. 39 as evidence that Aceon was on the Alabama PDL in 2003); Dkt. 111, Ex. 39 (AndroGel prescription insert).

is no evidence that these physicians ever voted on the status of Aceon or that, if they did, their votes were influenced by their dealings with SPI representatives. *Id.* SPI contends that there is absolutely no evidence of *effective* wooing of Alabama P&T Committee members. *Id.* at 14.

Relators, however, are not burdened with showing that SPI clearly wooed P&T Committee members and that it undoubtedly resulted in Aceon being placed on the PDL. They are burdened with coming forward with an issue of material fact. The court must determine whether a reasonable jury could determine, given the evidence at hand, that SPI wooed P&T Committee members and that this wooing influenced P&T committee members' decision to place Aceon on the Alabama PDL. The evidence of wooing is sparse. The fact that sales representatives called on physicians who were at some point on the P&T committee is insufficient, by itself, as obviously it is not unlawful for SPI to call on physicians who may prescribe its products. There is no evidence that SPI's calls to physicians who were on the P&T committee were disproportionate to the calls to other physicians. Additionally, even for the calls that indicate AWC was discussed, it is far from clear that these discussions related to off label use of Aceon since Aceon's label discusses AWC in animals. Similarly, there is no indication that it was unlawful to discuss ACT with a physician who was participating in that study. That being said, some of the evidence could signal wooing. It is a very close call, but the court finds that viewing the evidence in the light most favorable to Relators, a reasonable jury could find that SPI attempted to woo Alabama P&T committee members to get them to place Aceon on the Alabama PDL.

However, attempted wooing does not demonstrate a fact issue as to whether members who voted to place Aceon on the PDL did so because of SPI's wooing. While the court appreciates that it would be difficult to obtain direct evidence that the P&T committee members were improperly

influenced by SPI and only voted to place Aceon on the PDL because of this influence, the only circumstantial evidence of causation is the temporal proximity between this wooing and the placement on the PDL. There is no evidence that the physicians who were subject to the wooing were actually on the committee when the were wooed or when the committee voted to place Aceon on the PDL. There is also no evidence that these few physicians impacted the vote enough to get the entire committee to act. If the only issue were "is there a question of material fact as to whether SPI attempted to influence physicians to place Aceon on the Alabama PDL," then the answer would be yes. However, there must be a question of fact as to causation, and there is not enough for a reasonable jury to infer causation. Thus, SPI's motion for summary judgment on the P&T Committee Influence Theory as it relates to Aceon and Alabama is GRANTED.

4. Florida

Relators contend that Florida instituted a PDL in 2001 and that SPI exerted undue influence to get Florida to add Aceon to the PDL. Dkt. 420 at 16–17. A 2001 draft of a Florida Medicaid Action Plan indicates that SPI was looking for ways to "deal with the Florida Medicaid Program changes." Dkt. 420, Ex. 66 at 1. This document states that SPI spoke with a "very strong 'Pro Solvay' physician," who also happened to be a PROGRESS speaker, about nominating himself for the Florida P&T Committee. *Id.* The document also states that SPI "should consider utilizing the PROGRESS data to leverage a true 'Medical Need' for those patients that have a family history of stroke." *Id.* at 2. Additionally, it urges that SPI needed "to capitalize on this opportunity and detail those targeted prescribers who have significant Medicaid practices immediately and aggressively." *Id.*

The Florida P&T Committee reviewed ACE inhibitors like Aceon on August 25, 2001, and elected not to add Aceon to the PDL. Dkt. 420, Ex. 67. In September 2001, an internal memorandum indicates that an SPI sales representative planned to present the PROGRESS data to Provider Synergies, the pharmacy benefits manager for Florida's Medicaid program, in October 2001. Dkt. 420, Ex. 69 at 674673. Also in 2001, an SPI sales representative indicated that he planned to schedule a lunch and learn at the medical office of a P&T committee member and that he had set up a lunch and learn with another P&T committee member. Dkt. 420, Exs. 70, 71. A person appearing to be the representative's supervisor cautioned the representative to "be especially sensitive to the fact that [the P&T committee members] should be treated exactly as other[] physicians you call on. Please do not acknowledge their position on the committee or in an way appear to influence them beyond what you do on a normal, customary detail call. We canNOT lobby them with regard to Medicaid." Dkt. 420, Ex. 70.

On February 12, 2002, one of SPI's senior Government Affairs representatives created a Florida Medicaid Action Plan to get Aceon on Florida's PDL. Dkt. 420, Ex. 73. This document notes that in January 2002 SPI representatives met with individuals from Provider Synergies, one of whom was "compelled by PROGRESS data but stated that a new approach must be made first to Provider Synergies, Inc. to gain [Florida] P&T review." *Id.* at 4. The proposed options included preparing a new presentation "that includes potential savings from secondary stroke reductions for the state of [Florida]." *Id.*

On September 3, 2003, Florida's P&T Committee voted to add Aceon to its PDL. Dkt. 420, Ex. 61. The committee voted again to make Aceon a preferred product in 2004, and two of the physicians who had been targeted for lunch and learns voted to keep Aceon on the PDL. Dkt. 420,

Ex. 71. Aceon lost preferred status in July 2005, but regained it from March 2006 until April 2007. Dkt. 420, Exs. 74–80 (March, July, August, September, and November 2006 PDLs listing Aceon as a preferred Ace Inhibitor).

SPI points out that the Florida P&T Committee voted *not* to include Aceon on Florida's PDL in 2001, which is after some of the alleged wooing took place. Dkt. 456. SPI argues that any temporal connection between the alleged wooing and the September 2003 vote to include Aceon on the Florida PDL is too attenuated to support causation. *Id.*

The court agrees that the temporal connection between the evidence of wooing that was provided and the vote to include Aceon on the Florida PDL is insufficient. While Relators do provide a February 2002 plan to get Aceon on the PDL, the activities suggested in the plan are merely proposed. There is no evidence that any wooing took place after the initial vote not to include Aceon on the PDL other than discussions about PROGRESS with Provider Synergies in January 2002. Aceon was not approved for the PDL until September 2003. The placement on the PDL is too far removed from any of the alleged wooing to infer causation. Accordingly, SPI's motion for summary judgment on the P&T Committee Influence Theory as to Aceon and Florida is GRANTED.

5. Illinois

The State of Illinois implemented a PDL in 2002. Dkt. 420, Ex. 64 at 294–95. On March 1, 2002, SPI sent a dossier to Provider Synergies, which was the pharmacy benefit manger for the State of Illinois, that included information about AWC, prevention of secondary stroke, and the PROGRESS study—all of which is off-label information. Dkt. 420, Ex. 81. Aceon was on the Illinois PDL by October 2003. *See* Dkt. 420, Exs. 82–89. It remained on the PDL until October 2004. Dkt. 420, Ex. 90 (October 2004 Illinois PDL listing Aceon as non-preferred).

SPI points out first that there was nothing unlawful about its submission of the dossier to Provider Synergies, as Provider Synergies requested the information. *See* Dkt. 420, Ex. 81 (letter thanking Provider Synergies for its "interest in ACEON" and providing "clinical and economic data relating to this product"). Additionally, it argues that the dossier could not possibly have caused the Illinois P&T Committee to list Aceon on its PDL, as during the 18 months between SPI's sending of the dossier to Provider Synergies and Illinois listing Aceon on its PDL, there were 33 iterations of the PDL not including Aceon. Dkt. 456 at 11 (citing 396-8, Ex. 8 at Exs. 150-77).

The court agrees with SPI that a reasonable jury could not infer causation from these facts. Accordingly, SPI motion for summary judgment on the P&T Committee Influence Theory as to Aceon and Illinois is GRANTED.

6. Iowa

Iowa decided to implement its first PDL in 2003. Dkt. 420, Ex. 64 at109295 (noting that HF619, which passed in 2003, required the creation of a Medicaid PDL). Prior to this decision, in 2002, an SPI sales representative had numerous visits about Aceon with a physician who eventually voted to add Aceon to the Iowa PDL. Dkt. 420, Ex. 92 (call notes); Dkt. 420, Ex. 91 (Iowa P&T Committee minutes listing the physician as a member). According to the call notes, the sales representative covered a claim about Aceon's 24-hour efficacy, which Relators contend is related to SPI's off-label campaign.[16] Dkt. 420 at 20. Additionally, in November 2003, an SPI managed care

[16] The call notes state, specifically, "Aceon 24hr control. Better control, lower cost, split the 8mg dose." Dkt. 420, Ex. 92. Relators contend this is "directly related to [SPI's] off-label campaign." Dkt. 420 at 20. However, according the the complaint, the off-label issue with a 24-hour claim is if it is used in conjunction with a diabetic kidney message. *See* note 5, *supra*. The Aceon label indicates under "dosing and administration" that it "should be given at an initial dose of 4 mg once daily for 2 weeks." *See* http://www.accessdata.fda.gov/drugsatfda_docs/label/2005/020184s011lbl.pdf (cited in the Fifth Amended Complaint). Also, the "clinical pharmacology"

area manager reported in an internal email that he and an SPI managed care executive "worked ACS (PBM) to push [adding Aceon to the Iowa PDL] through." Dkt. 420, Ex. 93. According to Relators, "ACS (PBM)" means ACS was the pharmacy benefits manager for Iowa. *See* Dkt. 420 at 20. In 2004, Iowa added Aceon to its PDL as a preferred product effective December 24, 2004; it remained a preferred product until January 16, 2006. *See* Dkt. 310-19 (examples of Iowa PDLs). SPI points out that the calls to the physician were two years prior to Aceon being added to the PDL. Dkt. 456 at 14.

Here, there is no evidence that SPI unlawfully wooed P&T Committee members to get them to add Aceon to the Iowa PDL. First, the time lapse between the calls to the physician who was eventually on the P&T Committee and the implementation of the PDL is too great to infer causation. Moreover, Iowa did not even have a PDL at the time the calls were made, so SPI could not have been targeting the physician as a P&T committee member. Plus, there is no indication that the sales representative was violating any rules by telling the physician about twenty-four hour control. As to the internal email about "working ACS," the inferential leap from "working ACS" to unlawful wooing is too large for a reasonable jury to conclude that improper wooing caused the P&T Committee to place Aceon on the Iowa PDL. Accordingly, SPI's motion for partial summary judgment as to claims that SPI wooed the Iowa P&T Committee into including Aceon on the Iowa PDL is GRANTED.

---

section discusses how the maximum ACE inhibition of 80 to 90 percent is attained with an 8 mg dose for ten to twelve hours and that "[t]wenty-four hour ACE inhibition is about 60% after these doses." *Id.* Relators do not provide any evidence that this the twenty-four hour efficacy claim is a prohibited off-label message meant to induce P&T members into placing the drug on the Iowa PDL.

7. Louisiana

The state of Louisiana announced that it was creating a P&T committee in October 2001 and began reviewing drugs for formulary inclusion. Dkt. 420, Ex. 94 (letter from the State of Louisiana Department of Health and Hospitals). The letter specifically states that pharmaceutical manufacturers who make drugs in the categories that will be reviewed may submit a dossier. *Id.* Some SPI executives took part in a teleconference on February 8, 2002, to discuss submitting the Aceon dossier to Louisiana. Dkt. 420, Ex. 96. Relators note that the Aceon dossier includes off-label information about AWC and strokes. *See* Dkt. 420 & Ex. 81 (a March 1, 2002 Aceon dossier that was submitted to Provider Synergies).

In March 2002, two SPI executives attended the Louisiana P&T Committee meeting. Dkt. 420, EX. 97. There were also representatives from other pharmaceutical companies such as Wyeth, Bayer, and AstraZeneca in attendance. *Id.* The P&T Committee voted to make Aceon non-preferred at the June 2002 meeting. Dkt. 420, Ex. 98.

Relators provide call notes indicating that SPI sales representatives called on Louisiana P&T Committee members numerous times from 2001 through 2007. *See* Dkt. 420 at 21–22 & Exs. 101–07. They do not point to any "wooing" or off-label information being discussed during these sales calls. Relators contend that these calls, combined with the submission of the dossier, caused the Louisiana P&T committee to add Aceon as a preferred product in October 2004. Dkt. 420 at 22. Aceon was a preferred product on the Louisiana PDL from October 2004 until November 2005 and from October 2006 through October 2007. Dkt. 321-7 (July 14, 2003 initial Louisiana PDL indicating that Aceon required prior approval); Dkt. 321-7 (October 1, 2003 PDL indicating Aceon required prior approval); Dkt. 321-6 (April 1, 2004 PDL indicating that Aceon required prior approval);

Dkt. 321-6 (July 1, 2004 PDL indicating Aceon required prior approval); Dkt. 321-5 (October 1, 2004 PDL listing Aceon as preferred); Dkt. 321-5 (November 1, 2005 PDL indicating Aceon requires prior approval); Dkt. 321-4 (April 1, 2006 PDL indicating that prior approval was required for Aceon); Dkt. 321-3 (October 1, 2006 PDL listing Aceon as preferred); Dkt. 321-2 (April 1, 2007 PDL listing Aceon as preferred); Dkt. 321-1 (October 1, 2007 PDL indicating Aceon required prior approval).

The court disagrees with Relators' contentions. Provider Synergies requested that pharmaceutical companies send it dossiers. *See* Dkt. 420, Ex. 81 (indicating the dossier was being sent at Provider Synergies' request). Providing the requested information does not amount to "wooing." Moreover, the Louisiana P&T committee decided not to include Aceon on its PDL after receiving the dossier. As far as the sales calls, there is no indication that the sales representatives provided any information to these P&T committee members that was not provided to other physicians or that the information was in any way unlawful or constituted wooing. The P&T committee members are also physicians, and Relators have pointed to no rules that indicate that SPI was prohibited from discussing Aceon with these physicians simply because they were members of the P&T committee. Thus, SPI's motion for summary judgment on the P&T Committee Influence Theory as to Aceon and Louisiana is GRANTED.

8. South Carolina

South Carolina implemented a Medicaid PDL on May 19, 2004. Dkt. 420, Ex. 64. Relators provide call notes indicating that an SPI sales representative called on a physician who eventually became a South Carolina P&T committee member fourteen times in 2002.[17] *See* Dkt. 420 at 22 &

[17] Relators note that the sales representative did not document what was discussed during these visits, but they assert that the discussions must not have been strictly on-label and appropriate because the representative's 2001 performance appraisal praises her for implementing a "music and

n.23. On April 7, 2004, the Alabama P&T committee, which included the physician who was visited so many times in 2002, agreed to make Aceon a preferred drug on the South Carolina PDL. Dkt. 420, Ex. 109. Aceon remained preferred until December 2005. Dkt. 315-18 through 315-20.

This evidence simply is not sufficient to create an issue of material fact that SPI wooed South Carolina P&T committee members and that this influenced the committee to include Aceon on the South Carolina PDL. Even if the jury could draw a reasonable inference that the sales representative who visited one South Carolina doctor (who in 2004 became a P&T committee member) fourteen times in 2002 was wooing that future P&T committee member, the committee did not include Aceon on the PDL until April 2004. This time difference is too great to support causation based on temporal proximity. Accordingly, SPI's motion for summary judgment on the P&T Committee Influence Theory as to Aceon and South Carolina is GRANTED.

9. West Virginia

The West Virginia legislature approved the implementation of a PDL and drug utilization review program via H 4666 in 2002. Dkt. 420, Ex. 64. In November of that year, an SPI employee spoke at a West Virginia P&T committee meeting regarding Aceon and discussed the PROGRESS data. *See* Dkt. 420, Ex. 110 (P&T Committee minutes indicating that the representative "mentioned the outcomes of the PROGRESS Trial"). However, the West Virginia P&T committee voted to require prior authorization of Aceon at that meeting. *Id.* According to an SPI monthly activity report, on September 25, 2003, a physician who was also an SPI speaker made a presentation to Provider Synergies, which was the pharmacy benefits manager for West Virginia. Dkt. 420, Ex. 112 at 681479. The document states that the physician discussed ACT, PROGRESS, and another trial called

---

dash" program. Dkt. 420 at 22 n.23 (citing Dkt. 420, Ex. 108).

EUROPA, and that Provider Synergies then requested an Aceon dossier. *Id.* The document also indicates that West Virginia was having a P&T meeting on October 8, 2003. *Id.*

On November 10, 2004, the West Virginia P&T Committee voted to give Aceon preferred status. *See* Dkt. 420, Ex. 113 (minutes of November 10, 2004 P&T Committee meeting approving Aceon as a preferred ACE inhibitor). Aceon remained preferred for several months, but by October 2005, it was no longer preferred. *See, e.g.*, Dkt. 317-9 (October 29, 2003 PDL listing Aceon as non-preferred); Dkt. 317-6 (July 5, 2005 PDL listing Aceon as preferred); Dkt. 317-4 (PDL implemented on October 3, 2005 indicating Aceon was a non-preferred agent).

Dr. F became a member of the West Virginia P&T Committee in 2006.[18] Dkt. 420 at 23; Dkt. 420, Ex. 115 (West Virginia P&T committee minutes indicating Dr. F was a new member). Relators provide call notes of one of SPI's representatives that indicate that she called on Dr. F in 1999 and 2000 and discussed AWC, gave the physician an Aceon poem, may have provided a coffee maker, definitely provided an employee of the practice coffee and supplies, and provided a flyer about ACT. Dkt. 420, Ex. 114. On August 16, 2006, the West Virginia P&T committee, including Dr. F, voted to again add Aceon to the preferred ACE Inhibitors on the West Virginia PDL. Dkt. 420, Ex. 115 at 15. Aceon remained preferred until October 2007. *See, e.g.*, Dkt. 317-1 (West Virginia PDL posted on September 15, 2006 and implemented on October 2, 2006 listing Aceon as a preferred agent); Dkt. 316-14 (West Virginia PDL implemented October 1, 2007 not listing Aceon).

The court will now unpack this evidence. First, in 2002 an SPI representative spoke about Aceon at a P&T committee meeting, and the committee voted not to include Aceon as a preferred

[18] The court has changed the name of the physicians discussed in this order because the physician names are subject to a protective order.

drug on its PDL. Then, in 2003, a physician who had been an SPI speaker spoke to Provider Synergies about Aceon, and the committee, which met soon thereafter, decided not to include Aceon as a preferred drug on its PDL. About a year later, for some reason, the committee decided to make the drug preferred, which lasted about a year. Prior approval was required for Aceon for about a year, until a physician who had been wooed by SPI in 1999 and 2000—*six* years prior—became a member of the committee. Aceon became preferred that month, and remained preferred for about one more year. As to the first time Aceon was listed as preferred, the fact that the committee voted against Aceon after the first presentation and then it took another year after the second presentation to place Aceon on the list, after another intervening vote not to put it on the list, makes it illogical for any reasonable jury to conclude that the committee placed Aceon on the list because of these presentations. The evidence supporting undue influence the second time Aceon was placed on the PDL is even less persuasive. While certainly it appears that Dr. F was being wooed by an SPI sales representative in 1999 through 2000, he did not become a member of the West Virginia P&T committee for six more years. And, when he did become a member, there is no evidence of recent wooing. There is, essentially, no temporal link at all. SPI's motion for summary judgment on Relators' claim that SPI wooed West Virginia P&T Committee members to get them to place Aceon on the West Virginia PDL is GRANTED.

C. AndroGel

AndroGel is a testosterone gel that the FDA approved for the treatment of particular types of male hypogonadism in 2000. Dkt. 154 at 67–68 & Ex. 39. It "'is indicated for replacement therapy in males for conditions associated with a deficiency or absence of endogenous testosterone.'" Dkt.

154 at 68 (quoting the AndroGel original label). AndroGel is a gel that is applied once daily and can be absorbed through the skin. *Id.* at 69.

Relators contend that SPI decided to expand the market for AndroGel by expanding the definition of hypogonadism. *Id.* at 71. Thus, according to Relators, SPI began marketing AndroGel for a condition called "andropause," which Relators contend is a "dubious medical condition for which the FDA has never approved the drug." *Id.* at 74. Relators additionally contend that SPI has promoted AndroGel off label for "wasting" in HIV and AIDS patients, women, methadone and other opioid users, diabetics, the obese, and those suffering from depression, osteoporosis, and sexual dysfunction. *Id.* at 71, 82.

1. Expert Evidence

SPI argues that Relators only have evidence of damages for the P&T Committee Influence Theory for Ohio because Relators' damages expert only considered Florida, Michigan, Ohio, and Texas when calculating AndroGel damages and only had sufficient data to calculate damages for Ohio. Dkt. 396 & Ex. 3 ¶ 81. The expert states that she expects that all four states would have had lower utilization than they had if AndroGel had not been added to the PDL. *Id.* at 82. However, unlike with Aceon, she does not state in her amended expert report that she estimated damages for any states with regard to AndroGel. *See* Dkt. 396, Ex. 2 ¶ 5. Instead, she discusses only Ohio. *Id.* It is thus clear, as SPI contends, that there is no evidence of damages for any state other than Ohio. Accordingly, SPI's motion for summary judgment on the P&T Committee Influence Theory as to AndroGel and Florida, Loisiana, Maryland, Tennessee, Texas, West Virginia, and Wisconsin, is GRANTED.

2. Ohio

In May 2001, an SPI global affairs senior representative authored an email about SPI's "Ohio AndroGel presentation." Dkt. 420, Ex. 130. She noted that SPI had an AndroGel presentation with the Ohio P&T committee scheduled on July 25, 2001. *Id.* She stated that one of SPI's sales representatives was friends with Ohio Medicaid's director, who was "highly influential with the committee." *Id.* The Medicaid director had expressed concern with AndroGel's price and allegedly advised that the presentation should focus on AndroGel's clinical superiority. *Id.* SPI's global affairs senior representative discussed potential speakers for the meeting, including an opinion thought leader who wrote testosterone prescriptions for body building and, while writing prescriptions for all testosterone products, was "apparently a [sic.] Androgel supporter." *Id.* The "next steps" listed in the letter included identifying opinion thought leaders or champions to write letters or present at the meeting and identifying clinical information to submit in advance. *Id.*

In June 2001, an SPI regional account executive for managed care for Ohio, Michigan, and Indiana emailed the global affairs senior representative and informed her that he had found a speaker for the Ohio P&T Committee meeting. Dkt. 420, Ex. 132. Relators provide a draft of a letter to introduce the presentation to the Ohio Medicaid P&T Committee. Dkt. 420, Ex. 133. Relators imply that the letter provides unlawful information because it discusses AndroGel's effects on body mass, bone mineral density, libido, mood, and fatigue, but fails to mention hypogonadism. Dkt. 420. They do not, however, provide any evidence that this draft was ever sent to or received by the Ohio committee.

According to an internal SPI email, the presentation to the Ohio P&T committee was successful and Ohio removed the prior authorization requirement for AndroGel in 2001. Dkt. 420,

Ex. 129 at 364906. However, AndroGel was subject to prior authorization again at some point in 2003. Moreover, it appears that there was not an actual PDL in Ohio until 2003.[19] *See* Dkt. 420, Ex. 134 at 640141 (noting in a 2004 Managed Care Business Plan that Ohio, "[l]ike many other states," was "in the process of creating a preferred drug list" and that it would be "looking at specific drug classes throughout 2003-4").

At some point in 2003, SPI determined that Dr. C would be a good speaker for the Ohio P&T Committee. Dkt. 420 at Ex. 135 at 469559. A January 20, 2004, email from an SPI corporate account executive notes that Dr. C would receive a $1,000 honorarium for speaking to the Ohio P&T committee, and it outlines some of the key points for Dr. C to present. Dkt. 420, Ex. 137. It emphasizes that Dr. C should "stay away from discussion of using Androgel for lifestyle issues." *Id.* Relators point out that the email does not mention hypogonadism as a key point, even though AndroGel's indication was for the treatment of hypogonadism. Dkt. 420.

On February 4, 2004, Dr. C appeared before the Ohio P&T committee and discussed "the importance of testosterone therapy." Dkt. 420, Ex. 138. She noted that there was a black box warning on oral testosterone therapy, that there was a concern with surges and costs with injectable therapy, and that the benefits of a topical therapy (like AndroGel) included a lower and more stable hormone level and less potential for abuse. *Id.* The committee recommended covering topical testosterone, i.e. AndroGel, without prior authorization. *Id.* An internal SPI email discussing Dr. C's

[19] The court realizes that some states required prior authorization of certain drugs well before they implemented lists of preferred drugs. There is, however, a difference between keeping a drug *off* of a prior authorization list and getting it placed *on* a PDL or formulary, and the P&T Committee Influence Theory as stated in the fifth amended complaint relates to wooing physicians to get the drug placed *on* a PDL or formulary.

presentation in more detail indicates that an SPI employee worked with Dr. C on the material and that some of the items she discussed were off label.[20] Dkt. 420, Ex. 141.

First, Dr. C is not a member of the Ohio P&T committee, so whether SPI wooed her is immaterial to Relators' claim that SPI wooed P&T committee members. There is, however, some evidence that SPI worked with Dr. C to present off-label information to the committee. Thus, there may be an issue of material fact as to whether SPI unlawfully influenced the committee's decision. That being said, SPI argues that there is no evidence that AndroGel was ever listed as preferred on an Ohio PDL. *See* Dkt. 457. The documents Relators cite to show AndroGel was on the Ohio PDL are (1) an undated internal email stating that SPI "secured AndroGel positioning for Ohio Medicaid recipients"; and (2) a draft SPI memorandum stating that "AndroGel recently received preferred status on Ohio Medicaid." Dkt. 420, Exs. 141–42. While certainly not as good as having a copy of the Ohio PDL, particularly since there may be other barriers to the drug getting on the PDL after the committee votes for it, this evidence may be sufficient, drawing all inferences in favor of Relators, for a reasonable jury to conclude AndroGel was on the PDL. Because a jury could conclude that the P&T committee added AndroGel to the PDL and that the committee was influenced by off-label information provided by SPI, and because there is some evidence of damages, there is an issue of material fact as to this theory for AndroGel in Ohio. However, since the court has already dismissed

[20] The email notes that Dr. C's "positioning of Androgel" was based on, among other things, "[c]linical data of osteoporosis and fracture rate for men" and "[d]epression and the impact of osteoporosis on the elderly male," both of which were derived from an article by Wang. Dkt. 420, Ex. 141. Additionally, the pharmacoeconomic model she discussed was "provided by [an SPI representative] and fine tuned by Dr. C." *Id.* She also discussed various risks of oral therapy, how AndroGel could provide a consistent testosterone level, symptoms of low testosterone such as depression, and the peaks and troughs of injection therapy. *Id.*

all claims relating to AndroGel because they are barred due to the False Claims Act Public Disclosure Bar, the unresolved questions of fact as to this theory are of no consequence. *See* Dkts. 386, 585.

VI. CONCLUSION

SPI's motion for partial summary judgment on Relators' P&T Committee Influence Theory (Dkt. 395) is GRANTED. All of Relators' claims under this theory are DISMISSED WITH PREJUDICE.

Signed at Houston, Texas on February 8, 2016.

Gray H. Miller
United States District Judge